PATIENT INFORMATION LEAFLET

EPILIZINE can seriously harm an unborn child when taken during pregnancy. It can cause serious birth defects to body organs and/or body structures as well as harm the developing brain of the fetus and can also affect the way in which the child develops as it grows. Children whose mothers took EPILIZINE during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, be intellectually less able than other children, and have difficulties with language and memory.

Children whose mothers took EPILIZINE during pregnancy have an increased risk of developing autistic spectrum disorders, childhood autism and attention-deficit hyperactivity disorder (ADHD).

EPILIZINE treatment must be started and supervised by a doctor experienced in the treatment of epilepsy or bipolar disorder.

You must not take EPILIZINE if the risk minimisation measures (Pregnancy Prevention Programme) have not been explained to you and if you cannot commit to follow the pregnancy risk minimisation measures.

SCHEDULING STATUS: S3

EPILIZINE® CR 200 prolonged-release tablets:

Each tablet contains 133,2 mg sodium valproate and 58,0 mg valproic acid equivalent to 200 mg sodium valproate.

Sugar free.

EPILIZINE® CR 300 prolonged-release tablets:

Each tablet contains 199,8 mg sodium valproate and 87,0 mg valproic acid equivalent to 300 mg sodium valproate.

Sugar free.

EPILIZINE® CR 500 prolonged-release tablets:

Each tablet contains 333,0 mg sodium valproate and 145,0 mg valproic acid equivalent to 500 mg sodium valproate.

Sugar free.

Read all of this leaflet carefully before you start taking or are given EPILIZINE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EPILIZINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What EPILIZINE is and what it is used for
2. What you need to know before you take or are given EPILIZINE
3. How to take EPILIZINE
4. Possible side effects
5. How to store EPILIZINE
6. Contents of the pack and other information.

1. WHAT EPILIZINE IS AND WHAT IT IS USED FOR

EPILIZINE is used to treat epilepsy (fits) or used to treat bipolar disorders (severe mental illness) in adults.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OR ARE GIVEN EPILIZINE

Do not take EPILIZINE or give EPILIZINE to your child:

- If you or your child is hypersensitive (allergic) to sodium valproate (the active ingredient) or any of the other ingredients of EPILIZINE (see section 6).
- If you are breastfeeding your baby (see Pregnancy, breastfeeding and fertility).
- If you are pregnant or able to have a baby:
  - *For the treatment of epilepsy:*
    - If you or your female (girl) child is pregnant, unless there is no suitable alternative treatment (see Pregnancy, breastfeeding and fertility: Pregnancy – Important information for women).
    - If you or your female (girl) child is able to have a baby, unless the conditions of the pregnancy prevention programme are met (see Pregnancy, breastfeeding and fertility: Pregnancy – Important information for women).
  - *For the treatment of bipolar disorder:*
    - If you are pregnant.
    - If you are a woman able to have a baby, unless the conditions of the Pregnancy Prevention Programme are met (see Pregnancy – Important information for women).
- If you or your child has an active disease of the liver, including the following:
  - If you or your child has short- or long-term (severe) inflammation of the liver (hepatitis).
  - If you or your child (or any of your close relatives) has a past history of severe hepatitis (inflammation of the liver), especially when caused by medicines.
  - If you or your child suffers from liver porphyria (a very rare metabolic disease).
- If you or your child has been told you have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).
- If you or your child have a known metabolic disorder, i.e. a urea cycle disorder.
- If you have an inborn carnitine deficiency (a very rare metabolic disease) that is untreated.

If you think you or your child may have any of these problems, or if you have any doubt at all, consult your doctor before taking EPILIZINE or giving EPILIZINE to your child.

Warnings and precautions

Take special care with EPILIZINE:

- **If you are a woman or female adolescent able to have a baby:**
  - If you are a woman or female adolescent that is old enough to become pregnant, your doctor should only treat you with EPILIZINE if you are not pregnant and you fulfil the requirements of the Pregnancy Prevention Programme (see Pregnancy, breastfeeding and fertility: Pregnancy – Important information for women).
  - If you are taking EPILIZINE and you decide you want to start a family, talk to your doctor about this as soon as possible. Do not stop EPILIZINE or using birth control (contraception) until you have been able to discuss this with your doctor. You need to talk to your doctor about the risks for your baby's health while keeping your illness under control. Your doctor and you should agree on what to do with your treatment before you start trying for a baby (see Pregnancy, breastfeeding and fertility: Pregnancy – Important information for women).

- **If you have a female (girl) child using EPILIZINE:**
  Parents or caregivers of a female (girl) child treated for epilepsy with EPILIZINE, must contact the doctor once the female child using EPILIZINE experiences her first menstrual period.

- **If you are pregnant:**
  If you are pregnant, talk to your doctor immediately (see section 2).
- If you or your child develops a sudden illness, especially if it is within the first six months of treatment, and particularly if it includes repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, loss of appetite, nausea, jaundice (yellowing of the skin or whites of the eyes), swelling of the legs, worsening of your epilepsy or a general feeling of being unwell,

YOU SHOULD TELL YOUR DOCTOR IMMEDIATELY. EPILIZINE can affect the liver (and sometimes the pancreas) in a very small number of patients.

- The risk of liver damage is increased if EPILIZINE is taken by your child, less than 3 years of age, who is taking other anti-epileptic medicine at the same time or has other neurological or metabolic diseases and severe forms of epilepsy.
- Especially if your child is under 3 years of age, EPILIZINE should not be administered together with acetylsalicylic acid (aspirin).
- If you or your child taking EPILIZINE develops problems with balance and co-ordination, vomiting, feeling lethargic or less alert, tell your doctor immediately. This may be due to an increased amount of ammonia in your blood.
- Convulsions may become worse or happen more frequently whilst taking EPILIZINE. If this happens contact your doctor immediately.
- If you or your child has systemic lupus erythematosus (SLE – a rare disease of the immune system which affects skin, bones, joints and internal organs).
- If you or your child has been told that you have any metabolic disorders, particularly hereditary enzyme deficiency disorders such as a urea cycle disorder where too much ammonia builds up in the body.
- If you or your child has kidney problems. Your doctor may want to monitor the level of EPILIZINE in your body or give you a lower dose.
- If you or your child puts on weight, as your appetite may be increased. Talk to your doctor about how this will affect you or your child.
- If you or your child has diabetes, EPILIZINE may affect the results of urine tests.
- If at any time you or your child has thoughts of harming or killing yourself, immediately contact your doctor.
- If you or your child drinks alcohol. Alcohol intake is not recommended during treatment with EPILIZINE (see EPILIZINE with food, drink and alcohol).
- If you or your child has been told that you have carnitine palmitoyl transferase type II deficiency.

- If you or your child has been told that there is a genetic problem caused by a mitochondrial disorder in your family.
- If you or your child experiences worsening of epilepsy control in terms of frequency or severity whilst taking EPILIZINE, contact your doctor immediately.
- Your doctor or your child's doctor may wish to do blood tests before you or your child starts taking EPILIZINE and during your treatment.
- EPILIZINE should be used with caution in male and female children less than 18 years of age, for the treatment of epilepsy.
- EPILIZINE should only be used in adult males who plan to father a child if alternative treatment options are not suitable.
- EPILIZINE should not be used in children and adolescents under the age of 18 years for the treatment of mania associated with bipolar disorders.

Other medicines and EPILIZINE

Always tell your health care provider if you or your child is taking any other medicine. (This includes all complementary or traditional medicines.)

Some other medicines may influence the effect of EPILIZINE or vice versa. These include:

- neuroleptic agents (used to treat psychological disorders) – EPILIZINE may increase the effects of these medicines
- antidepressant therapy (medicines used to treat depression, including monoamine oxidase inhibitors)
- benzodiazepines, used as sleeping tablets or to treat anxiety
- other medicines used to treat epilepsy, including phenobarbital (phenobarbitone), phenytoin, primidone, lamotrigine, carbamazepine and felbamate cannabidiol (used to treat epilepsy and other conditions)
- zidovudine (used to treat HIV infections and AIDS)

- mefloquine and chloroquine (used to treat or prevent malaria) – may increase the likelihood of a fit. Before travelling to a malaria area, you should get advice from your doctor or pharmacist on the most appropriate tablets for prevention.
- salicylates (aspirin), especially in children below 3 years of age (see Warnings and precautions)
- anticoagulants (used to prevent blood clots)
- cimetidine (used to treat ulcers)
- erythromycin, rifampicin, linezolid (used to treat infections)
- carbapenem antibiotics such as imipenem, ertapenem and meropenem (antibiotics used to treat bacterial infections). The combination of EPILIZINE and carbapenems should be avoided because it may decrease the effect of EPILIZINE.
- rufinamide (used to treat convulsions)
- colestyramine (used to treat excessive high blood lipid levels)
- protease inhibitors (used to treat HIV), such as lopinavir and ritonavir
- acetazolamide (used to treat glaucoma, seizures or brain swelling). The combination with EPILIZINE may cause a build-up of ammonia in the body.
- temozolomide (used to treat cancer)
- when used in combination with olanzapine (used to treat psychiatric disorders) the following effects may occur: Neutropenia – a blood disorder leading to a reduced chance of fighting infection, dry mouth, increased appetite and weight gain, problems with speech, sleepiness or extreme tiredness.
- propofol (used for anaesthesia)
- nimodipine (used in brain bleeds)
- estrogen-containing medicines (including some birth control tablets) (see Warnings and precautions). Monitor seizures (fits) and mood control when you or your child starts or stops taking estrogen-containing tablets.

- metamizole (used to treat pain and fever) may reduce blood levels of valproate (in EPILIZINE). Blood tests or close monitoring of seizure (fits) and mood control is recommended.
- methotrexate (used to treat cancer and inflammatory diseases)
- some anti-infectives that contain pivalate (e.g. pivampicillin, adefovir dipivoxil).

These medicines and others may be affected by EPILIZINE or affect how well it works. You or your child may need different amounts of medicine or you may need to take different medicines. Your doctor will advise you.

EPILIZINE with food, drink and alcohol

Alcohol intake is not recommended during treatment with EPILIZINE (see Take special care with EPILIZINE).

It is preferable to take EPILIZINE with or after food to reduce a feeling of sickness that may occur after taking EPILIZINE.

Swallow controlled-release formulation tablets whole, but do not use aerated mineral water (see section 3).

Pregnancy, breastfeeding and fertility

Pregnancy

You must not use EPILIZINE if you are pregnant or breastfeeding your baby (see section 2).

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking EPILIZINE.

Important information for women and female children able to have a child and pregnant women:

If you or your female (girl) child is pregnant, you must not use EPILIZINE, unless your doctor has determined there is no suitable alternative treatment.

If you or your female (girl) child is able to have a baby, you must not use EPILIZINE unless the conditions of the Pregnancy Prevention Programme are met.

EPILIZINE can be harmful to unborn children when taken by a woman during pregnancy. EPILIZINE can cause serious birth defects and can affect the way in which the child develops as it grows.

The conditions of the Pregnancy Prevention Programme require that before EPILIZINE is prescribed for you or your child:

- Your doctor must explain what might happen to your baby if you become pregnant while taking EPILIZINE. You need to ensure you understand these risks.
- You will be asked to perform a pregnancy test before starting EPILIZINE, or thereafter if needed. This is to make sure you are not pregnant.
- Effective birth control (contraception) will be recommended for you to avoid becoming pregnant while taking EPILIZINE.
- Your doctor will assess your understanding of contraception and the need for contraception without interruption during the entire duration of treatment with EPILIZINE.
- Your doctor will review your treatment regularly (at least once a year).
- **Your doctor will ask you to read and sign an Annual Risk Acknowledgement Form** to make sure you are well aware and have understood all the risks related to the use of EPILIZINE during pregnancy and are aware and understand the recommendations to avoid becoming pregnant.
- A Patient Guide will be given to you by your doctor. **Make sure you read the Patient Guide that you will receive from your doctor.**
- **You will also receive a Patient Card from your pharmacist to remind you of the risks of using EPILIZINE in pregnancy.**

- Your doctor will explain what to do if you decide later that you want to have a baby. If you are planning a baby, you must first discuss this with your doctor. You must not stop taking EPILIZINE or interrupt your method of contraception until you have discussed this with your doctor.
- Parents or caregivers of a female (girl) child treated with EPILIZINE, must contact the doctor once the female child using EPILIZINE experiences her first menstrual period.

Please choose the situation which applies to you or your child and read the description that follows:

- I AM STARTING TREATMENT WITH EPILIZINE (First prescription)
- I AM TAKING EPILIZINE AND I AM NOT PLANNING TO HAVE A BABY
- I AM TAKING EPILIZINE AND I AM PLANNING TO HAVE A BABY
- I AM PREGNANT AND I AM TAKING EPILIZINE.

I AM STARTING TREATMENT WITH EPILIZINE (First prescription)

- If this is the first time you have been prescribed EPILIZINE, your doctor would have explained the risks to an unborn child if you become pregnant.
- If you are able to have a baby or once you are able to have a baby, you will need to make sure that you use an effective method of birth control (contraception) throughout your treatment. Talk to your doctor or family planning clinic if you need advice on birth control (contraception).
- Pregnancy must be excluded before start of treatment with EPILIZINE through the result of a pregnancy (blood) test, to be confirmed by your doctor.
- You must discuss appropriate methods of birth control (contraception) with your doctor.
- EPILIZINE has no effect on the efficacy of your oral contraceptive pill.
- Some estrogen-containing birth control pills may lower valproate levels (the active ingredient of EPILIZINE) in your blood (see Other medicines with EPILIZINE).

- You must make sure you are using an effective method of birth control (contraception) during your entire treatment.
- You must schedule regular appointments (at least annually) with a doctor experienced in the management of epilepsy or bipolar disorder.
- Tell your doctor at once if you are pregnant or think you might be pregnant.
- Tell your doctor if you plan to become pregnant.
- It is important you contact your doctor if your female (girl) child, treated with EPILIZINE, experiences her first menstrual period.

I AM TAKING EPILIZINE AND I AM NOT PLANNING TO HAVE A BABY

If you are continuing treatment with EPILIZINE and you do not plan to have a baby, make sure you are using an effective method of birth control (contraception) without interruption during your entire treatment with EPILIZINE. Talk to your doctor or family planning clinic if you need advice on contraception.

- Make sure you are using an effective method of contraception during your entire treatment.
- You must schedule regular (at least annually) appointments with a doctor experienced in the management of epilepsy or bipolar disorder.
- Tell your doctor **immediately** if you are pregnant or think you might be pregnant.
- Tell your doctor if you plan to become pregnant.
- Parents or caregivers of a female child (girl) child treated with EPILIZINE, must contact the doctor once the female child using EPILIZINE experiences her first menstrual period.

I AM TAKING EPILIZINE AND I AM PLANNING TO HAVE A BABY

If you are on treatment with EPILIZINE and planning to have a baby, first schedule an appointment with your doctor. You should talk to your doctor a long enough time before you become pregnant so that you and your doctor can put several actions in place to ensure that your pregnancy goes as smoothly as possible, and any risks to you and your unborn child are reduced as much as

possible. Your doctor may prescribe another medicine for your epilepsy which may have less risk for your baby.

- Do not stop taking EPILIZINE or your birth control (contraception) until you have discussed this with your doctor. Your doctor will advise you on when you can stop your contraception.
- Babies born to mothers who have been on EPILIZINE are at serious risk of birth defects and problems with development, which can be seriously debilitating.
- Your doctor may want to adjust your treatment and/or prescribe dietary supplements of folic acid. Folic acid may lower the risk of spina bifida (a birth defect) and early miscarriage. However, it is unlikely that folic acid will reduce the risk of birth defects associated with EPILIZINE use.
- You must not stop taking EPILIZINE unless your doctor agrees, as there are severe risks to yourself and your developing baby if your epilepsy is not controlled.
- If you are pregnant, or think you might be pregnant, see your doctor **immediately**.

I AM PREGNANT AND I AM TAKING EPILIZINE

Women should not become pregnant while receiving EPILIZINE. You should use an effective method of birth control (contraception) and consult your doctor before planning pregnancy.

- EPILIZINE has no effect on the efficacy of your oral contraceptive pill.
- Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant. Your doctor will advise you further.
- Do not stop taking EPILIZINE unless your doctor tells you to as your condition may become worse. During pregnancy, should a mother suffer from a serious type of seizure, where the oxygen supply to her and her unborn baby may be cut off, the risk of death to the mother and unborn child is increased. Your doctor will advise you further.
- Make sure you are referred to a doctor experienced in the treatment of epilepsy or bipolar disorder to re-assess your treatment options.

- You must get thorough counselling on the risks of EPILIZINE during pregnancy, including malformations and developmental effects in children.
- Make sure you are referred to a doctor for prenatal monitoring in order to detect possible occurrences of malformations.

The risks of EPILIZINE when taken during pregnancy:

- EPILIZINE crosses the placental barrier in humans.
- Babies born to mothers who are taking EPILIZINE, are at serious risk of birth defects and problems with development which can be seriously debilitating.
- It is known that in women who take EPILIZINE, around 10 babies in every 100 will have birth defects, as compared to 2 – 3 babies in every 100 born to women who do not have epilepsy.
- These birth defects of your developing baby include spina bifida (condition where bones of the spine are not properly developed), craniofacial defects (face and skull malformations), malformation of the limbs, heart, kidney and sexual organ malformations, hypospadias (malformation of the urethra) and multiple anomalies involving various body systems.
- Hearing problems or deafness has been reported in children exposed to EPILIZINE during pregnancy and monitoring for signs and symptoms of hearing loss is recommended.
- Eye malformations have been reported in children exposed to valproate, as in EPILIZINE, during pregnancy in association with other congenital malformations. These eye malformations may affect vision.
- Children born to a mother who took EPILIZINE during pregnancy, may have impaired physical and mental development or autistic disorders. There is some evidence that children may be more likely to develop symptoms of attention-deficit hyperactivity disorder (ADHD).
- It is estimated that up to 30 to 40 % of preschool children whose mothers took EPILIZINE during pregnancy may have problems with early childhood development. Children affected

can be slow to walk and talk, less intellectually able than other children, and have difficulty with language and memory.

- It is therefore essential that you discuss your treatment with your doctor if you are thinking of becoming pregnant or tell your doctor as soon as you know you are pregnant.
- Your doctor may want to adjust your treatment and/or prescribe dietary supplements of folate.
- You must not stop taking EPILIZINE unless your doctor agrees, as there are severe risks to yourself and your developing baby if you have uncontrolled epilepsy.

Newborn babies of mothers who took EPILIZINE during pregnancy may have:

- Blood clotting problems (blood not clotting very well). This may appear as bruising, or bleeding which takes a long time to stop.
- Hypoglycaemia (low blood sugar levels).
- Hypothyroidism (underactive thyroid gland, which can cause tiredness or weight gain).
- Withdrawal syndrome (agitation, irritability, hyper-excitability, jitteriness, increased muscle movement, muscle problems, tremor, convulsions and feeding problems) when taken during the last trimester of pregnancy.

Important advice for male patients able to father a child

Potential risk related to taking EPILIZINE in the 3 months prior to conception

A study suggests that if you take valproate in the 3 months prior to conception, your child may have a higher risk for impaired mental and/or motor development compared to children born to fathers who used lamotrigine or levetiracetam, other medicines that can be used to treat your disease. In this study, about 5 in 100 children had such disorders when born from fathers treated with valproate, as in EPILIZINE, and about 3 in 100 children when born from fathers treated with the other medicines. There are no data on this potential risk to children fathered more than 3 months after stopping valproate treatment (the time needed for new sperm to be formed).

As a precautionary measure, your doctor will discuss with you:

- the potential risk when fathering a child if you are treated with EPILIZINE
- the need to use effective contraception (birth control) for you and your female partner during the treatment and for 3 months after stopping EPILIZINE
- the need to consult your doctor to discuss alternative treatment options, as soon as you are planning to father a child and before discontinuing contraception (birth control)
- to not donate sperm during treatment and for 3 months after stopping treatment.

Do not stop your treatment without talking to your doctor. If you stop your treatment, your symptoms may become worse. If your female partner becomes pregnant while you used valproate in the 3 months prior to conception, both of you should contact the doctor for counselling.

You should get regular (at least annual) appointments with your doctor. During this visit your doctor will make sure you acknowledge the risk and precautions associated with EPILIZINE use.

Breastfeeding

EPILIZINE passes into the breast milk. You should not breastfeed your baby if you are taking EPILIZINE (see section 2).

Fertility

EPILIZINE can cause infertility in both men and women that may not always be reversible.

Driving and using machines

EPILIZINE may cause drowsiness or light-headedness. Taking other medicines used to treat fits or calm emotional and mental health problems may increase sleepiness. It is not always possible to predict to what extent EPILIZINE may interfere with your daily activities. Make sure you know

how you react to EPILIZINE before you drive a car, operate tools or machinery, or do anything else that could be dangerous if you are drowsy or light-headed.

EPILIZINE contains sodium

EPILIZINE CR 200 contains 18,43 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 0,92 % of the recommended maximum daily dietary intake of sodium for an adult.

EPILIZINE CR 300 contains 27,65 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1,38 % of the recommended maximum daily dietary intake of sodium for an adult.

EPILIZINE CR 500 contains 46,08 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2,30 % of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE EPILIZINE

Do not share medicines prescribed for you or your child with any other person.

Always take or give your child EPILIZINE exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

EPILIZINE treatment must be started and supervised by a doctor experienced in the treatment of epilepsy.

Swallow EPILIZINE CR tablets whole (do not crush or chew them), with a drink of water (not with aerated mineral water), usually with or after meals. EPILIZINE CR is a controlled-release formulation and may be given once or twice daily.

Epilepsy

Adults

The usual dose of EPILIZINE is between 1 000 mg and 2 000 mg per day but may be increased to 2 500 mg per day. This quantity can be divided and taken in 2 separate doses, e.g. half in the morning and half in the evening.

Children

Children over 20 kg*:*

The usual dose of EPILIZINE is based on the child's weight as an amount of EPILIZINE for each kg of body weight. The usual dose is between 20 mg and 30 mg for each kg of body weight but may be increased to 35 mg for each kg of body weight per day. This quantity can be divided and given in 2 separate doses, e.g. half in the morning and half in the evening.

Children under 20 kg*:*

The usual dose of EPILIZINE is based on the child's weight as an amount of EPILIZINE for each kg of body weight. The usual dose is 20 mg for each kg of body weight. This quantity can be divided and given in 2 separate doses e.g. half in the morning and half in the evening.

EPILIZINE for the treatment of mania associated with bipolar disorders in adults

The usual initial dose is 1 000 mg/day.

Elderly patients

Your dosage will be determined by the seizure control it gives you and be recommended by your doctor.

Patients with kidney problems

Your doctor may decide to adjust your or your child's dose.

Female children, women of childbearing potential and pregnant women

Pregnant women as well as female children and women that are able to have a baby must not use EPILIZINE unless their doctor determined that there is no suitable alternative or the conditions for the Pregnancy Prevention Programme are met (see section 2).

EPILIZINE does not reduce the effectiveness of hormonal contraceptives. Estrogen-containing contraceptives may however increase the clearance of valproate, which may result in potentially decreased EPILIZINE effectiveness (see Other medicines and EPILIZINE).

If you have the impression that the effect of EPILIZINE is too strong or too weak, tell your doctor or pharmacist.

Make sure you keep your regular check-up appointments. They are very important, as your dosage may need to be changed.

When treatment is first started, you may be prescribed a lower dose. This is because some patients need less EPILIZINE than others to control their fits. Your doctor will increase the dosage until your condition is controlled. Because of this, it is very important that you follow the instructions your doctor has given you about how much to take. Blood tests may be needed.

Combined therapy

If you are taking other medicines to control your epilepsy at the same time as EPILIZINE CR your doctor may increase the dose of EPILIZINE CR by 5 mg to 10 mg for each kg of body weight per day.

If you take or your child receives more EPILIZINE than required

An overdose of EPILIZINE is dangerous. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Signs of overdosage or taking too much of EPILIZINE include:

- Coma, poor muscle tone resulting in limpness of the body.
- Inability to breathe properly.
- Having little or no reflexes when tested using a reflex hammer.
- Constriction of the pupils – pupils become smaller.
- Metabolic acidosis – which occurs when the body produces excessive quantities of acid or the kidneys are unable to remove enough acid from the body.
- Decrease in blood pressure and subsequent shutdown of the body due to shortage of blood flow.
- Death may occur in case of a large overdose.

Symptoms in cases of overdose:

- This may vary but might include seizures, very high pressures within the skull.
- The content of sodium in EPILIZINE may cause hypernatraemia (excessive sodium content in the body) when taken in excess.

If you forget to take or missed a dose of EPILIZINE

If you or your child missed a dose of EPILIZINE, take it or give it to your child as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not take or give your child a double dose to make up for a forgotten dose.

If you have forgotten to take or give your child several doses, immediately contact your doctor.

If you or your child stops taking or receiving EPILIZINE

Do not stop taking or giving your child EPILIZINE or alter the dose without checking with your doctor. If you stop taking or giving your child EPILIZINE without your doctor's advice your condition or your child's condition may get worse.

4. POSSIBLE SIDE EFFECTS

EPILIZINE can have side effects.

Not all side effects reported for EPILIZINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following serious side effects:

- allergic reactions, which cause joint pain, skin rashes and fever (systemic lupus erythematosus)
- an allergy-triggered swelling with painful itchy welts (angioedema); most often around the eyes, lips, tongue and throat with difficulty in breathing or swallowing and sometimes the hands and feet
- syndrome with medicine rash, fever, lymph node enlargement and possible impairment of other organs (DRESS syndrome)
- repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, loss of appetite, severe upper stomach pain, nausea, jaundice (yellowing of the skin or whites of the eyes), swelling of the legs, worsening of your epilepsy or a general feeling of being unwell
- severe decrease in white blood cells or bone marrow failure, sometimes revealed by fever and breathing difficulty or recurring infection
- blood clotting problems (bleeding for longer than normal)
- bruising or bleeding for no reason
- EPILIZINE may also cause decreased platelet or red blood cell count (pancytopenia)

- memory impairment and cognitive disorders (changes in mood, loss of memory, lack of concentration)
- loss of consciousness (coma)
- underactive thyroid gland, which causes tiredness or weight gain (hypothyroidism)
- breathing difficulty and pain due to inflammation of the lungs (pleural effusion)
- changes in consciousness level, bizarre behaviour associated or not with more frequent or more severe fits, loss of drive, particularly if phenobarbital (phenobarbitone) and topiramate are taken at the same time or if the EPILIZINE dose has been increased suddenly
- changes in the amount of ammonia in the blood. Symptoms of this condition are feeling and being sick, problems with balance and co-ordination, feeling lethargic or less alert
- confusion that may be due to decreased levels of sodium in your blood
- extrapyramidal disorder (feeling shaky, [tremor], sleepy or unsteady when walking, or jerky muscle movements)
- blisters and skin detachment (skin flaking away)
- rapid, uncontrollable movements of the eyes
- muscle pain and muscle weakness (rhabdomyolysis)
- an increase in the number and severity of convulsions

These are all **serious side effects**. You may need urgent medical attention.

Other side effects are:

Frequent

- vomiting, nausea (feeling sick) or stomach ache, diarrhoea
- dizziness
- hearing problems
- headache
- hair loss; when it grows back it may be curlier than before

- hair, including body and facial hair, grows more than normal in women (polycystic ovarian syndrome)
- menstrual changes (changes in a woman's period)
- weight gain (as your appetite may be increased)
- decrease in carnitine levels (shown in blood or muscular tests)
- aggression, agitation, disturbance in attention
- tingling or numbness of the hands or feet
- gingival (gum) problems, especially overgrowth
- sore mouth, swollen mouth, mouth ulcers and burning feeling of your mouth (stomatitis).

Less frequent

- fainting, hallucinations (seeing, feeling or hearing things that are not there)
- skin reactions such as rashes
- acne, lowered voice
- hair colour changes, nail and nail bed disorders
- swelling of the feet and legs (oedema)
- kidney problems, bedwetting or increased need to pass urine
- passing a lot of urine and feeling thirsty (Fanconi syndrome)
- abnormal behaviour, restlessness/hyperactivity and learning disorder
- impairment of fertility
- decrease in body temperature
- there have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis, or take steroids
- double vision.

Frequency not known

- Pelger-Huet anomaly (an inherited blood condition, where white blood cell cores have an unusual shape and structure), which your doctor will determine with a blood test.

Children:

The safety profile of EPILIZINE in children is comparable to adults, but some adverse reactions are more severe or more often observed in children. There is a particular risk of severe liver damage in infants and young children, especially under the age of 3 years. Young children are also at particular risk of pancreatitis. These risks decrease with increasing age (see Warnings and precautions). Psychiatric disorders such as aggression, agitation, disturbance in attention, abnormal behaviour, psychomotor hyperactivity and learning disorder are mainly observed in children.

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or other health care provider.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can report side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of EPILIZINE.

5. HOW TO STORE EPILIZINE

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store EPILIZINE CR in the original package at or below 25 °C.

Protect from light and moisture.

EPILIZINE CR may spoil if not stored properly. It is very important to keep the tablets in their protective foil until just before you take them.

Do not take or use EPILIZINE CR after the expiry date stated on the pack.

Return unused or expired medicines to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What EPILIZINE CR contains

The active substance is sodium valproate.

The other ingredients are:

Ethyl cellulose, hydrated silica, hypromellose and violet coat, containing: hypromellose, titanium dioxide, macrogol 400, indigo-carmine aluminium lake FD&C Blue No. 2, erythrosine BS aluminium lake, iron oxide black.

What EPILIZINE CR looks like and contents of the packs

EPILIZINE CR 200: unmarked oblong, violet, film-coated tablets, nominally 13,25 x 6,75 mm.

EPILIZINE CR 300: unmarked oblong, violet, film-coated tablets, nominally 15 x 7,5 mm.

EPILIZINE CR 500: unmarked oblong, violet, film-coated tablets, nominally 17,25 x 9,75 mm

EPILIZINE CR 200, EPILIZINE CR 300 and EPILIZINE CR 500 tablets are packed in silver aluminium foil blister strips with a leaflet into printed cardboard boxes of 56 or 100 tablets.

Holder of Certificate of Registration

sanofi-aventis south africa (pty) ltd

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EPILIZINE CR 500: A39/2.5/0040

Date of registration

04 December 2009.

PASIËNTINLIGTINGSBLAD

EPILIZINE kan ernstige skade aan ’n ongebore kind doen wanneer dit tydens swangerskap geneem word. Dit kan ernstige geboortedefekte aan liggaamsorgane en/of liggaamstrukture veroorsaak, asook die ontwikkelende brein van die fetus skade aandoen en dit kan ook die groeiende kind se ontwikkeling affekteer. Kinders van moeders wat EPILIZINE tydens swangerskap geneem het, mag probleme met ontwikkeling in hul vroeë kinderjare ondervind. Kinders wat geaffekteer word, kan laat begin om te loop en te praat, intellektueel minder bekwaam wees as ander kinders, en probleme met spraak en geheue ondervind.

Kinders van moeders wat EPILIZINE tydens swangerskap geneem het, het ’n verhoogde risiko om outismespektrumversteurings, outisme van die kinderjare en aandaggebrek-hiperaktiwiteitsteuring (AGHS/ADHD) te ontwikkel.

’n Mediese praktisyn met ondervinding in die behandeling van epilepsie of bipolêre versteuring, moet EPILIZINE-behandeling begin en toesig hou.

Jy moenie EPILIZINE neem indien die maatreëls om risiko te minimaliseer (Swangerskapvoorkomingsprogram) nie aan jou verduidelik is nie en as jy jouself nie kan verbind tot die nakoming van die maatreëls om die risiko vir swangerskap te minimaliseer nie.

SKEDULERINGSTATUS: S3

EPILIZINE® CR 200 verlengdevrystellingstablette:

Elke tablet bevat 133,2 mg natriumvalproaat en 58,0 mg valproïensuur, ekwivalent aan 200 mg natriumvalproaat.

Suikervry.

EPILIZINE® CR 300 verlengdevrystellingstablette:

Elke tablet bevat 199,8 mg natriumvalproaat en 87,0 mg valproïensuur, ekwivalent aan 300 mg natriumvalproaat.

Suikervry.

EPILIZINE® CR 500 verlengdevrystellingstablette:

Elke tablet bevat 333,0 mg natriumvalproaat en 145,0 mg valproïensuur, ekwivalent aan 500 mg natriumvalproaat.

Suikervry.

Lees hierdie inligtingsblad noukeurig deur voordat jy EPILIZINE begin neem of ontvang.

- Hou hierdie inligtingsblad. Dit mag nodig wees om dit later weer te lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- EPILIZINE is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik wees vir hulle, al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingsblad

1. Wat is EPILIZINE en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy EPILIZINE neem of ontvang
3. Hoe om EPILIZINE te neem
4. Moontlike newe-effekte
5. Hoe om EPILIZINE te berg
6. Inhoud van die verpakking en ander inligting.

1. WAT IS EPILIZINE EN WAARVOOR WORD DIT GEBRUIK

EPILIZINE word gebruik om epilepsie (toevalle) te behandel of dit word gebruik om bipolêre versteuring (erge geestesversteuring) by volwassenes te behandel.

2. WAT JY MOET WEET VOORDAT JY EPILIZINE NEEM OF ONTVANG

Moenie EPILIZINE neem of vir jou kind gee nie:

- Indien jy of jou kind hipersensitief (allergies) vir natriumvalproaat (die aktiewe bestanddeel) of vir enige van die ander bestanddele van EPILIM is (sien afdeling 6).
- Indien jy jou baba borsvoed (sien Swangerskap, borsvoeding en vrugbaarheid).
- Indien jy swanger is of in staat is om swanger te raak:
  - *Vir die behandeling van epilepsie:*
    - Indien jy of jou vroulike kind (dogter) swanger is, tensy daar geen geskikte alternatiewe behandeling is nie (sien Swangerskap, borsvoeding en vrugbaarheid: Swangerskap – Belangrike inligting vir vrouens).
    - Indien jy of jou vroulike kind (dogter) in staat is om ’n baba te hê, tensy die voorwaardes van die Swangerskapvoorkomingsprogram nagekom word (sien Swangerskap, borsvoeding en vrugbaarheid: Swangerskap – Belangrike inligting vir vrouens).
  - *Vir die behandeling van bipolêre versteuring:*
    - Indien jy swanger is.
    - Indien jy is vrou is wat nog kan swanger raak, tensy die voorwaardes van die Swangerskapvoorkomingsprogram nagekom word (sien Swangerskap, borsvoeding en vrugbaarheid: Swangerskap – Belangrike inligting vir vrouens).
- Indien jy of jou kind ’n aktiewe lewersiekte het, insluitende die volgende:
  - Indien jy of jou kind kort- of langtermyn (erge) inflammasie van die lewer (hepatitis) het.
  - Indien jy of jou kind (of enige naverwante familielede) ’n geskiedenis van erge hepatitis (inflammasie van die lewer) het, veral as dit deur medisynes veroorsaak is.
  - Indien jy of jou kind aan porfirie van die lewer ly (’n uiters seldsame metaboliese siekte).
- Indien jy of jou kind ingelig is dat julle ’n genetiese probleem het wat deur ’n mitochondriale versteuring veroorsaak word (bv. Alpers-Huttenlocher-sindroom).

- Indien jy of jou kind ’n bekende metaboliese versteuring het, naamlik ’n versteuring van die ureumsiklus.
- Indien jy ’n aangebore karnitiengebrek (’n uiters seldsame metaboliese siekte) het, wat nie behandel word nie.

Indien jy dink dat jy of jou kind enige van hierdie probleme mag hê, of indien jy enigsins twyfel, konsulteer jou dokter voordat jy EPILIZINE neem of EPILIZINE vir jou kind gee.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met EPILIZINE:

- **Indien jy ’n vrou of vroulike adolessent is wat kan swanger raak:**
  - Indien jy ’n vrou of ’n vroulike adolessent is wat oud genoeg is om swanger te raak, behoort jou dokter jou alleenlik met EPILIZINE te behandel indien jy nie swanger is nie en jy aan die vereistes van die Swangerskapvoorkomingsprogram voldoen (sien Swangerskap, borsvoeding en vrugbaarheid: Swangerskap – Belangrike inligting vir vrouens).
  - Indien jy EPILIZINE neem en jy besluit jy wil met ’n gesin begin, praat so gou as moontlik met jou dokter hieroor. Moenie ophou om EPILIZINE te neem of voorbehoeding (kontrasepsie) te gebruik voordat jy kans gehad het om dit met jou dokter te bespreek nie. Dit is noodsaaklik dat jy met jou dokter praat oor die risiko’s vir jou baba se gesondheid, terwyl jou siekte steeds onder beheer gehou word. Jy en jou dokter moet saamstem rakende jou behandeling voordat jy probeer om swanger te raak (sien Swangerskap, borsvoeding en vrugbaarheid: Swangerskap – Belangrike inligting vir vrouens).
- **Indien jy ’n vroulike kind (dogter) het wat EPILIZINE gebruik:**
  Die ouers of versorgers van ’n vroulike kind (dogter) wat met EPILIZINE vir epilepsie behandel word, moet die dokter kontak sodra sy haar eerste maandstonde kry.
- **Indien jy swanger is:**

Indien jy swanger is, sê onmiddellik vir jou dokter (sien afdeling 2).

- Indien jy of jou kind skielik ’n siekte ontwikkel, veral as dit binne die eerste ses maande van behandeling is, en veral as dit herhaalde braking, buitensporige moegheid, buikpyn, lomerigheid, swakheid, verlies aan aptyt, naarheid, geelsug (vergeling van die vel of die wit van die oë), swelling van die bene, verergering van jou epilepsie of ’n algemene gevoel van ongesteldheid insluit, **MOET JY ONMIDDELLIK JOU DOKTER DAAROOR INLIG**. EPILIZINE kan by ’n baie klein aantal pasiënte die lewer (en soms ook die pankreas) aantas.
- Die risiko van lewerskade is groter indien EPILIZINE deur jou kind wat jonger as 3 jaar oud is geneem word, wat ander anti-epileptiese medisyne gepaardgaande neem of ander neurologiese of metaboliese siektes en erge vorms van epilepsie het.
- Veral indien jou kind jonger as 3 jaar oud is, behoort EPILIZINE nie saam met asetielsalisielsuur (aspirien) toegedien te word nie.
- Indien jy of jou kind wat EPILIZINE neem probleme met balans en koördinasie ontwikkel, opgooi, lomerig of minder waaksaam voel, sê onmiddellik vir jou dokter. Dit kan weens verhoogde ammoniakvlak in die bloed wees.
- Konvulsies kan erger raak of meer gereeld voorkom terwyl EPILIZINE geneem word. Indien dit gebeur, kontak onmiddellik jou dokter.
- Indien jy of jou kind sistemiese lupus eritematose het (SLE – ’n seldsame siekte van die immuunstelsel wat die vel, bene, gewrigte en inwendige organe affekteer).
- Indien jy of jou kind ingelig is dat julle enige metaboliese versteurings het, veral ’n aangebore ensiemgebrekversteuring, soos ’n ureumsiklusversteuring, waar te veel ammoniak in die liggaam ophoop.
- Indien jy of jou kind nierprobleme het. Jou dokter kan die vlak van EPILIZINE in jou liggaam monitor of vir jou ’n laer dosis gee.
- Indien jy of jou kind gewig optel, omdat julle aptyt verhoog mag wees. Praat met jou dokter oor hoe dit jou of jou kind gaan affekteer.
- Indien jy of jou kind diabetes het, mag EPILIZINE die resultate van urientoetse affekteer.

- Indien jy of jou kind te eniger tyd gedagtes van selfbesering of selfdood sou kry, kontak onmiddellik jou dokter.
- Indien jy of jou kind alkohol drink. Inname van alkohol word nie aanbeveel tydens behandeling met EPILIZINE nie (sien EPILIZINE met kos, drinkgoed en alkohol).
- Indien jy of jou kind ingelig is dat julle ’n karnitienpalmitoïeltransferase tipe II-gebrek het.
- Indien jy of jou kind ingelig is dat daar ’n genetiese probleem in julle familie is wat deur ’n mitochondriale versteuring veroorsaak word.
- Indien die beheer van jou of jou kind se epilepsie verswak in terme van frekwensie of ernstigheidsgraad terwyl EPILIZINE geneem word, sê onmiddellik vir jou dokter.
- Jou dokter of jou kind se dokter gaan moontlik bloedtoetse wil laat doen voordat jy of jou kind begin om EPILIZINE te ontvang, sowel as gedurende die behandeling.
- EPILIZINE behoort met omsigtigheid gebruik te word vir die behandeling van epilepsie by manlike sowel as vroulike kinders wat jonger as 18 jaar oud is.
- EPILIZINE moet alleenlik by volwasse mans wat nog beplan om ’n kind te verwek gebruik word indien alternatiewe opsies vir behandeling nie geskik is nie
- EPILIZINE behoort nie by kinders en adolessente onder die ouderdom van 18 jaar vir die behandeling van manie geassosieer met bipolêre versteurings, gebruik te word nie

Ander medisynes en EPILIZINE

Sê altyd vir jou gesondheidsorgdeskundige indien jy of jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisynes in.)

Party ander medisynes mag die effek van EPILIZINE beïnvloed, of omgekeerd. Dit sluit in:

- neuroleptiese middels (word gebruik om psigologiese versteurings te behandel) – EPILIZINE kan die effekte van hierdie medisyne verhoog
- antidepressantterapie (medisynes wat gebruik word om depressie te behandel, insluitende monoamienoksidase-inhibeerders)

- bensodiasepiene, wat gebruik word as slaaptablette of om angs te behandel
- ander medisynes wat gebruik word om epilepsie te behandel, insluitende fenobarbitaal (fenobarbitoon), fenitoïen, primidoon, lamotrigien, karbamasepien en felbamaat
- kannabidiol (gebruik om epilepsie en ander toestande te behandel)
- sidovudien (gebruik om MIV-infeksies en Vigs te behandel)
- meflokien en chlorokien (gebruik om malaria te behandel of te voorkom) mag die waarskynlikheid van ’n toeval verhoog. Voordat jy na ’n malariagebied reis, behoort jy advies van jou of jou kind se dokter of apteker te kry oor die mees geskikte tablette vir voorkomende behandeling.
- salisilate (aspirien), veral by kinders jonger as 3-jarige ouderdom (sien Waarskuwings en voorsorgmaatreëls)
- antikoagulante (gebruik om bloedklonte te voorkom)
- simetidien (gebruik om ulkusse te behandel)
- eritromisien, rifampisien, linesolied (gebruik om infeksies te behandel)
- karbapenem-antibiotika soos imipenem, ertapenem en meropenem (antibiotika wat gebruik word om bakteriële infeksies te behandel). Die kombinasie van EPILIZINE en karbapenemme moet vermy word omdat dit die effek van EPILIZINE mag verminder.
- rufinamied (gebruik om konvulsies te behandel)
- kolestiramien (gebruik om oormatig hoë vlakke van lipiede [vet] in die bloed te behandel)
- protease-inhibeerders (gebruik om MIV te behandel), soos lopinavir en ritonavir
- asetasoolamied (gebruik om gloukoom, toevalle of swelling van die brein te behandel). Die kombinasie met EPILIZINE mag ophoping van ammoniak in die liggaam veroorsaak.
- temosolomied (gebruik om kanker te behandel)
- wanneer dit in kombinasie met olansapien gebruik word (gebruik om psigiatriese versteurings te behandel), kan die volgende effekte voorkom: Neutropenie – ’n bloedversteuring wat kan lei tot ’n belemmerde vermoë om infeksie te bekamp, droë mond, verhoogde aptyt en gewigstoename, probleme met spraak, slaperigheid of buitensporige moegheid.

- propofol (gebruik vir narkose)
- nimodipien (gebruik vir breinbloedings)
- estrogeen-bevattende medisynes (insluitende party voorbehoedpille) (sien Waarskuwings en voorsorgmaatreëls). Monitor toevalle (stuipe) en beheer van gemoedstoestand wanneer jy begin of ophou om estrogeen-bevattende tablette te neem.
- metamisool (gebruik om pyn en koors te behandel) kan bloedvlakke van valproaat (in EPILIZINE) verlaag. Bloedtoetse of streng monitering van toevalbeheer (stuipe) en beheer van gemoedstoestand word aanbeveel.
- metotreksaat (gebruik om kanker en inflammatoriese siektes te behandel)
- sommige middels teen infeksie wat pivalaat bevat (bv. pivampisillien, adefovirdipivoksiel).

Hierdie en ander medisynes mag deur EPILIZINE geaffekteer word, of affekteer hoe goed dit werk. Jy of jou kind kan verskillende hoeveelhede van die medisyne benodig, of kan moontlik ’n ander medisyne moet neem. Jou dokter sal vir jou raad gee.

EPILIZINE met kos, drinkgoed en alkohol

Inname van alkohol tydens behandeling met EPILIZINE word nie aanbeveel nie (sien Neem spesiale sorg met EPILIZINE).

EPILIZINE moet verkieslik met of na ete geneem word om die gevoel van naarheid te verminder wat kan voorkom nadat EPILIZINE geneem is.

Sluk die beheerdevrystellingstablette heel in, maar nie met belugte mineraalwater nie (sien afdeling 3).

Swangerskap, borsvoeding en vrugbaarheid

Swangerskap

Indien jy swanger is of jou baba borsvoed, moet jy nie EPILIZINE gebruik nie (sien afdeling 2).

Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy EPILIZINE neem.

Belangrike inligting vir vrouens en vroulike kinders wat kan swanger raak, en swanger vrouens:

Indien jy of jou vroulike kind (dogter) swanger is, moet julle nie EPILIZINE gebruik nie, tensy jou dokter vasgestel het dat daar geen geskikte alternatiewe behandeling beskikbaar is nie.

Indien jy of jou vroulike kind (dogter) in staat is om ’n kind te hê, moet EPILIZINE nie gebruik word nie, tensy die voorwaardes van die Swangerskapvoorkomingsprogram nagekom word.

EPILIZINE kan skadelik vir die ongebore kind wees indien dit aan ’n vrou toegedien word terwyl sy swanger is. EPILIZINE kan ernstige geboortedefekte veroorsaak, en dit kan ook die groeiende kind se ontwikkeling affekteer.

Voordat EPILIZINE vir jou of jou kind voorgeskryf word, vereis die voorwaardes van die Swangerskapvoorkomingsprogram die volgende:

- Jou dokter moet vir jou verduidelik wat met jou baba kan gebeur indien jy swanger raak terwyl jy EPILIZINE neem. Jy moet seker maak dat jy hierdie risiko’s verstaan.
- Jy gaan gevra word om ’n swangerskapstoets te doen voordat jy begin om EPILIZINE te gebruik, of daarna indien nodig. Dit is om seker te maak dat jy nie swanger is nie.
- Doeltreffende geboortebeperking (kontrasepsie) gaan aanbeveel word sodat jy kan verhoed om swanger te raak terwyl jy EPILIZINE gebruik.
- Jou dokter gaan bepaal of jy kontrasepsie en die noodsaaklikheid vir kontrasepsie sonder onderbreking tydens die volle duur van die behandeling met EPILIZINE, verstaan.
- Jou dokter gaan jou behandeling gereeld hersien (ten minste een keer per jaar).
- **Jou dokter gaan jou vra om ’n “Jaarlikse Risiko-erkenningsvorm” te lees en te onderteken,** om seker te maak dat jy goed bewus is van en al die risiko’s verstaan wat

verband hou met die gebruik van EPILIZINE tydens swangerskap, en bewus is van al die aanbevelings oor hoe om swangerskap te vermy en dit verstaan.

- Jou dokter gaan vir jou ’n Pasiëntgids gee. **Maak seker dat jy die Pasiëntgids lees.**
- **Jy sal ook ’n Pasiëntkaart van jou apteker ontvang, om jou te herinner aan die risiko’s gekoppel aan die gebruik van EPILIZINE tydens swangerskap.**
- Jou dokter gaan vir jou verduidelik wat jy moet doen indien jy later sou besluit dat jy ’n baba wil hê. Indien jy beplan om swanger te raak, moet jy dit eers met jou dokter bespreek. Moenie ophou om EPILIZINE te neem of jou metode van kontrasepsie onderbreek nie, totdat jy kans gehad het om dit met jou dokter te bespreek.
- Die ouers of versorgers van ’n vroulike kind (dogter) wat met EPILIZINE behandel word, moet die dokter kontak sodra die vroulike kind wat EPILIZINE gebruik, haar eerste maandstonde kry.

Kies asseblief die situasie wat op jou of jou kind van toepassing is en lees die beskrywing wat daarop volg:

- EK BEGIN BEHANDELING MET EPILIZINE (Eerste voorskrif)
- EK NEEM EPILIZINE EN EK IS NIE VAN PLAN OM ’N BABA TE HÊ NIE
- EK NEEM EPILIZINE EN EK BEPLAN OM ’N BABA TE HÊ
- EK IS SWANGER EN EK NEEM EPILIZINE.

EK BEGIN BEHANDELING MET EPILIZINE (Eerste voorskrif)

- Indien dit die eerste keer is wat EPILIZINE vir jou voorgeskryf is, sou jou dokter vir jou die risiko’s wat dit vir ’n ongebore kind inhou indien jy swanger sou word, verduidelik het.
- Indien jy kan swanger raak of sodra jy kan swanger raak, sal jy moet seker maak dat jy ’n doeltreffende metode van geboortebeperking (kontrasepsie) dwarsdeur jou behandeling gebruik. Bespreek dit met jou dokter of gesinsbeplanningkliniek indien jy advies rakende geboortebeperking (kontrasepsie) nodig het.

- Swangerskap moet uitgesluit word voordat behandeling met EPILIZINE begin word deur middel van ’n swangerskapstoets (bloedtoets), wat deur jou dokter bevestig moet word.
- Jy moet gepaste metodes van geboortebeperking (kontrasepsie) met jou dokter bespreek.
- EPILIZINE het geen effek op die doeltreffendheid van jou mondelikse voorbehoedpil nie.
- Party voorbehoedpille wat estrogeen bevat, kan die bloedvlak van valproaat (die aktiewe bestanddeel in EPILIZINE) verlaag (sien Ander medisynes met EPILIZINE).
- Jy moet seker maak dat jy ’n doeltreffende metode van geboortebeperking (kontrasepsie) vir die volle duur van jou behandeling gebruik.
- Jy moet gereeld (ten minste jaarliks) ’n afspraak met ’n dokter maak wat ondervinding in die bestuur van epilepsie of bipolêre versteuring het.
- Sê dadelik vir jou dokter indien jy swanger is of dink dat jy swanger mag wees.
- Sê vir jou dokter indien jy beplan om swanger te raak.
- Dit is belangrik dat jy jou dokter kontak indien jou vroulike kind (dogter) wat met EPILIZINE behandel word, haar eerste maandstonde kry.

EK NEEM EPILIZINE EN EK IS NIE VAN PLAN OM ’N BABA TE HÊ NIE

Indien jy behandeling met EPILIZINE voortsit en jy nie beplan om ’n baba te hê nie, moet jy seker maak dat jy sonder onderbreking ’n doeltreffende metode van geboortebeperking (kontrasepsie) vir die volle duur van jou behandeling met EPILIZINE gebruik. Bespreek dit met jou dokter of personeel by die gesinsbeplanningkliniek indien jy advies oor kontrasepsie nodig het.

- Maak seker dat jy ’n doeltreffende metode van kontrasepsie vir die volle duur van jou behandeling gebruik.
- Jy moet gereeld (ten minste jaarliks) ’n afspraak met ’n dokter maak wat ondervinding in die bestuur van epilepsie of bipolêre versteuring het.
- Sê **onmiddellik** vir jou dokter indien jy swanger raak of dink dat jy swanger mag wees.
- Sê vir jou dokter indien jy beplan om swanger te raak.

- Die ouers of versorgers van ’n vroulike kind (dogter) wat met EPILIZINE behandel word, moet die dokter kontak sodra die vroulike kind wat EPILIZINE gebruik, haar eerste maandstonde kry.

EK NEEM EPILIZINE EN EK BEPLAN OM ’N BABA TE HÊ

Indien jy op behandeling met EPILIZINE is en beplan om ’n baba te hê, moet jy eers ’n afspraak met jou dokter skeduleer. Jy behoort lank genoeg voor jy swanger raak met jou dokter te praat, sodat jy en jou dokter verskeie stappe kan neem om te verseker dat jou swangerskap so glad as moontlik gaan verloop en dat enige risiko’s vir jou en jou baba soveel as moontlik verminder word. Jou dokter mag ’n ander medisyne vir jou epilepsie voorskryf wat minder risiko vir jou baba mag inhou.

- Moenie ophou om EPILIZINE te neem of jou geboortebeperking (kontrasepsie) staak nie, totdat jy dit met jou dokter bespreek het. Jou dokter gaan jou adviseer wanneer jy kan ophou om voorbehoeding te gebruik.
- Babas wat gebore word van moeders wat EPILIZINE gebruik het, het ’n ernstige risiko van geboortedefekte en ontwikkelingsprobleme, wat erge gestremdheid kan veroorsaak.
- Jou dokter gaan moontlik jou behandeling aanpas en/of dieetaanvullings van foliensuur voorskryf. Foliensuur kan die risiko van spina bifida (’n geboortedefek) en vroeë miskraam verlaag. Dit is egter onwaarskynlik dat foliensuur die risiko van geboortedefekte wat met die gebruik van EPILIZINE gepaard gaan, sal verminder.
- Jy moenie ophou om EPILIZINE te ontvang nie, tensy jou dokter saamstem, omdat dit ernstige risiko’s vir jouself en jou ontwikkelende baba inhou indien jou epilepsie nie beheer word nie.
- Indien jy swanger is of dink dat jy moontlik swanger mag wees, moet jy **onmiddellik** jou dokter gaan sien.

EK IS SWANGER EN EK NEEM EPILIZINE

Vrouens behoort nie swanger te raak terwyl hulle EPILIZINE ontvang nie. Jy behoort ’n doeltreffende metode van geboortebeperking (kontrasepsie) te gebruik en jou dokter te raadpleeg voordat jy swangerskap beplan.

- EPILIZINE het geen effek op die doeltreffendheid van jou mondelikse voorbehoedpil nie.
- Skeduleer ’n dringende afspraak met jou dokter indien jy swanger is of dink dat jy swanger mag wees. Jou dokter gaan jou verder adviseer.
- Moenie ophou om EPILIZINE te gebruik nie, tensy jou dokter vir jou sê om dit te doen, omdat jou toestand mag vererger. Indien ’n moeder tydens swangerskap ’n ernstige soort toeval sou kry, waar die suurstoftoevoer na haar en haar ongebore baba moontlik afgesny kan word, word die risiko van sterfte vir die moeder en die ongebore kind verhoog. Jou dokter sal jou verder adviseer.
- Maak seker dat jy verwys word na ’n dokter wat ondervinding in die behandeling van epilepsie of bipolêre versteuring het, om jou behandelingsopsies te herevalueer.
- Jy moet deeglike berading ontvang oor die risiko’s van EPILIZINE gedurende swangerskap, insluitende misvormings en ontwikkelingseffekte by kinders.
- Maak seker dat jy na ’n dokter verwys word vir voorgeboortelike monitering om die moontlike voorkoms van misvormings op te spoor.

Die risiko’s van EPILIZINE wanneer dit tydens swangerskap geneem word:

- EPILIZINE kruis die plasentale skans by mense.
- Babas wat gebore word van moeders wat EPILIZINE tydens hul swangerskap ontvang het, is blootgestel aan ernstige risiko van geboortedefekte en probleme met ontwikkeling, wat erge gestremdheid kan veroorsaak.
- Dit is bekend dat by vrouens wat EPILIZINE neem, ongeveer 10 uit elke 100 babas geboortedefekte gaan hê, in vergelyking met 2 – 3 uit elke 100 babas by vrouens wat nie epilepsie het nie.

- Hierdie geboortedefekte wat mag ontstaan by jou ontwikkelende baba, sluit in spina bifida (’n toestand waar die bene van die ruggraat nie behoorlik ontwikkel het nie), defekte van die skedel en gesig (gesig- en skedelmisvormings), misvorming van die ledemate, hart, niere en geslagsorgane, hipospadie (misvorming van die uretra) en talryke anomalieë wat verskeie liggaamstelsels betrek.
- Gehoorprobleme of doofheid is by kinders wat aan EPILIZINE blootgestel is tydens swangerskap gerapporteer en dit word aanbeveel dat vir tekens en simptome van gehoorverlies gemonitor word.
- Misvormings van die oog is gerapporteer by kinders wat tydens swangerskap aan valproaat, soos in EPILIZINE, blootgestel is, gepaardgaande met ander aangebore misvormings. Hierdie oogmisvormings kan sig affekteer.
- Kinders gebore van moeders wat EPILIZINE tydens swangerskap ontvang het, mag belemmerde fisieke en geestesontwikkeling of outistiese versteurings hê. Daar is bewyse dat kinders meer geneig kan wees om simptome van aandaggebrek-hiperaktiwiteitsteuring (AGHS/ADHD) te ontwikkel.
- Dit word beraam dat soveel as 30 tot 40 % van voorskoolse kinders wie se moeders EPILIZINE gedurende swangerskap ontvang het, probleme mag hê met ontwikkeling tydens die vroeë kinderjare. Kinders wat aangetas is, mag laat begin om te loop en te praat, minder intellektueel bekwaam wees as ander kinders en probleme met taal en geheue ondervind.
- Dit is dus noodsaaklik dat jy jou behandeling met jou dokter bespreek indien jy dit oorweeg om swanger te raak of dat jy jou dokter inlig sodra jy weet dat jy swanger is.
- Jou dokter sal moontlik jou behandeling wil aanpas en/of dieetaanvullings van folaat voorskryf.
- Jy moenie ophou om EPILIZINE te neem nie tensy jou dokter saamstem, omdat dit ernstige risiko’s vir jouself en jou ontwikkelende baba inhou indien jy ongekontroleerde epilepsie het.

Pasgebore babas van moeders wat EPILIZINE tydens swangerskap geneem het, mag die volgende hê:

- Bloedstollingsprobleme (bloed stol nie behoorlik nie). Dit kan gesien word as kneusing, of bloeding wat lank neem om te stop.
- Hipoglukemie (lae bloedsuikervlakke).
- Hipotiroïdisme (onderaktiewe skildklier, wat moegheid en gewigstoename kan veroorsaak).
- Onttrekkingsindroom (agitasie, prikkelbaarheid, uitermatige opgewondenheid, rusteloosheid, toename in spierbewegings, spierprobleme, tremor, konvulsies en voedingsprobleme) wanneer dit gedurende die laaste trimester van swangerskap gebruik is.

Belangrike advies vir manlike pasiënte wat ’n kind kan verwek

Moontlike risiko wat verband hou met die gebruik van EPILIM in die 3 maande wat bevrugting voorafgaan

’n Studie dui daarop dat indien jy valproaat neem in die 3 maande voordat bevrugting plaasvind, jou kind ’n hoër risiko van belemmerde verstandelike en/of motoriese ontwikkeling mag hê, in vergelyking met kinders van vaders wat lamotrigien of levetirasetaam, ander medisynes wat gebruik kan word om jou siekte te behandel, geneem het. In hierdie studie het omtrent 5 uit 100 kinders van vaders wat met valproaat behandel is, soos in EPILIM, en omtrent 3 uit 100 kinders van vaders wat met die ander medisynes behandel is, sulke versteurings gehad. Daar is geen data beskikbaar rakende hierdie moontlike risiko vir kinders wat meer as 3 maande nádat behandeling met valproaat gestaak is, verwek is nie (die tydperk wat nodig is vir nuwe spermselle om gevorm te word).

As ’n voorsorgmaatreël gaan jou dokter die volgende met jou bespreek:

- die moontlike risiko indien ’n kind verwek sou word terwyl jy met EPILIM behandel word

- die noodsaaklikheid vir jou en jou vroulike geslagsmaat om doeltreffende kontrasepsie (voorbehoeding) te gebruik gedurende die behandeling en vir 3 maande nadat EPILIM gestaak is
- die noodsaaklikheid dat jy jou dokter konsulteer om alternatiewe behandelingsopsies te bespreek sodra jy beplan om ’n kind te verwek en voordat kontrasepsie (voorbehoeding) gestaak word
- om nie tydens behandeling en vir 3 maande ná staking van behandeling sperm te skenk nie.

Moenie jou behandeling staak sonder om dit eers met jou dokter te bespreek nie. Jou simptome kan erger raak indien jy jou behandeling staak. Indien jou vroulike geslagsmaat swanger raak en jy valproaat in die 3 maande voor bevrugting gebruik het, moet julle albei die dokter kontak vir berading.

Jy behoort jou dokter gereeld te konsulteer (ten minste jaarliks). Gedurende die besoek sal jou dokter verseker dat jy bewus is van die risiko’s en voorsorgmaatreëls wat met die gebruik van EPILIM gepaard gaan.

Borsvoeding

EPILIZINE word in borsmelk uitgeskei. Jy behoort nie jou baba te borsvoed indien jy EPILIZINE neem nie (sien afdeling 2).

Vrugbaarheid

EPILIZINE kan onvrugbaarheid veroorsaak by sowel mans as vrouens, wat nie altyd omkeerbaar is nie.

Bestuur en gebruik van masjiene

EPILIZINE kan lomerigheid of lighoofdigheid veroorsaak. Die neem van ander medisynes wat gebruik word om toevalle te behandel of emosionele en geestesgesondheidprobleme te kalmeer, kan slaperigheid vererger. Dit is nie altyd moontlik om te voorspel tot watter mate EPILIZINE met jou daaglikse aktiwiteite mag inmeng nie. Maak seker dat jy weet hoe jy op EPILIZINE reageer voordat jy ’n motor bestuur, gereedskap of masjinerie hanteer of enigiets anders doen wat vir jou gevaarlik kan wees indien jy lomerig of lighoofdig is.

EPILIZINE bevat natrium

EPILIZINE CR 200 bevat 18,43 mg natrium (bestanddeel van tafelsout) in elke tablet. Dit is gelykstaande aan 0,92 % van die aanbevole maksimum daaglikse inname van natrium vir ’n volwassene.
EPILIZINE CR 300 bevat 27,65 mg natrium (bestanddeel van tafelsout) in elke tablet. Dit is gelykstaande aan 1,38 % van die aanbevole maksimum daaglikse inname van natrium vir ’n volwassene.
EPILIZINE CR 500 bevat 46,08 natrium (bestanddeel van tafelsout) in elke tablet. Dit is gelykstaande aan 2,30 % van die aanbevole maksimum daaglikse inname van natrium vir ’n volwassene.

3. HOE OM EPILIZINE TE NEEM

Moenie medisynes wat vir jou of jou kind voorgeskryf is, met enigiemand anders deel nie.

Jy moet altyd EPILIZINE neem of dit vir jou kind gee presies volgens jou dokter se aanwysings. Bespreek dit met jou dokter of apteker indien jy onseker is.

’n Dokter wat spesialiseer in die behandeling van epilepsie moet die behandeling met EPILIZINE begin en toesig hou daaroor.

Sluk die EPILIZINE CR-tablette heel in (moenie dit fyndruk of kou nie), met ’n bietjie water (nie belugte mineraalwater nie), gewoonlik met of na maaltye. EPILIZINE CR is ’n formulering met beheerde vrystelling en kan een of twee keer daagliks geneem word.

Epilepsie

Volwassenes

Die gebruiklike dosis EPILIZINE is tussen 1 000 mg en 2 000 mg per dag, maar dit kan verhoog word tot 2 500 mg per dag. Hierdie hoeveelheid kan in een dosis gegee word of dit kan verdeel word en in 2 aparte dosisse gegee word, bv. helfte in die oggend en helfte in die aand.

Kinders

Kinders swaarder as 20 kg:

Die gebruiklike dosis EPILIZINE word op die kind se gewig gebaseer as ’n hoeveelheid EPILIZINE vir elke kilogram liggaamsgewig. Die gebruiklike dosis is tussen 20 mg en 30 mg per kg liggaamsgewig, maar dit kan verhoog word tot 35 mg vir elke kg liggaamsgewig per dag. Hierdie hoeveelheid verdeel word en in 2 aparte dosisse gegee word, bv. helfte in die oggend en helfte in die aand.

Kinders onder 20 kg:

Die gebruiklike dosis EPILIZINE word op die kind se gewig gebaseer as ’n hoeveelheid EPILIZINE vir elke kilogram liggaamsgewig. Die gebruiklike dosis is 20 mg vir elke kg liggaamsgewig. Hierdie hoeveelheid moet verdeel word en in 2 aparte dosisse gegee word, bv. helfte in die oggend en helfte in die aand.

EPILIZINE vir die behandeling van manie wat met bipolêre versteurings gepaard gaan by volwassenes

Die gebruiklike aanvangsdosis is 1 000 mg/dag.

Bejaarde pasiënte

Jou dosering sal bepaal word op grond van die toevalbeheer wat dit bied en gaan deur jou dokter aanbeveel word.

Pasiënte met nierprobleme

Jou dokter kan besluit om jou of jou kind se dosis aan te pas.

Vroulike kinders, vrouens wat nog vrugbaar is en swanger vrouens

Swanger vrouens, sowel as meisies en vrouens wat nog kan swanger raak, moenie EPILIZINE gebruik nie, behalwe as hul dokter vasgestel het dat daar geen geskikte alternatief is nie of as die voorwaardes van die Swangerskapvoorkomingsprogram nagekom word (sien afdeling 2).

EPILIZINE verlaag nie die doeltreffendheid van hormonale voorbehoedmiddels nie. Estrogeen-bevattende voorbehoedmiddels kan egter die opruiming van valproaat versnel, wat moontlik kan veroorsaak dat EPILIZINE se doeltreffendheid verminder (sien Ander medisynes en EPILIZINE).

Indien jy die indruk kry dat die effek van EPILIZINE te sterk of te swak is, sê dit vir jou dokter of apteker.

Maak seker dat jy jou gereelde opvolgondersoeke nakom. Dit is baie belangrik, aangesien dit nodig mag wees dat jou dosis aangepas word.

Wanneer behandeling aanvanklik begin word, kan ’n laer dosis vir jou voorgeskryf word. Dit is omdat party pasiënte minder EPILIZINE nodig het as ander om hulle toevalle te beheer. Jou dokter gaan jou dosis verhoog totdat jou toestand onder beheer is. Dit is dus baie belangrik dat jy jou dokter se aanwysings rakende die dosis streng nakom. Bloedtoetse kan nodig wees.

Kombinasieterapie

Indien jy terselfdertyd as EPILIZINE CR ander medisynes neem om jou epilepsie te beheer, kan jou dokter die dosis EPILIZINE CR met 5 mg tot 10 mg vir elke kg liggaamsgewig per dag verhoog.

Indien jy of jou kind meer EPILIZINE ontvang as wat nodig is

'n Oordosis van EPILIZINE is gevaarlik. In geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Tekens van oordosering of dat te veel EPILIZINE geneem is, sluit in:

- Koma, swak spiertonus wat slapheid van die liggaam veroorsaak.
- Onvermoë om behoorlik asem te haal.
- Min of geen reflekse is teenwoordig nie wanneer daar met 'n reflekshamer getoets word.
- Vernouing van die pupille – die pupille word kleiner.
- Metaboliese asidose – wat voorkom wanneer die liggaam oormatige hoeveelhede suur produseer of as die niere nie in staat is om genoeg suur uit die liggaam te verwyder nie.
- Daling in bloeddruk en daaropvolgende ineenstorting van die liggaam as gevolg van 'n tekort aan bloedvloei.
- 'n Groot oordosis kan noodlottig wees.

Simptome in gevalle van oordosis:

- Dit mag wissel, maar kan toevalle en baie hoë druk binne die skedel insluit.
- Die natriuminhoud van EPILIZINE kan hipernatremie (oormatige natriuminhoud in die liggaam) veroorsaak wanneer dit in oormaat geneem word.

Indien ’n dosis EPILIZINE oorgeslaan is

Indien jy of jou kind ’n dosis EPILIZINE oorgeslaan het, neem dit of gee dit vir jou kind sodra jy daarvan onthou. Indien dit egter amper tyd is vir die volgende dosis, moet die dosis wat vergeet is, oorgeslaan word.

Moenie ’n dubbele dosis neem of vir jou kind gee om op te maak vir ’n vergete dosis nie.

Indien jy vergeet het om etlike dosisse te neem of om dit vir jou kind te gee, moet jy onmiddellik jou dokter kontak.

Indien jy of jou kind ophou om EPILIZINE te gebruik

Moenie ophou om EPILIZINE te neem of vir jou kind te gee, of die dosis wysig, sonder om eers jou dokter te raadpleeg nie. Indien jy EPILIZINE staak of dit nie vir jou kind gee nie, sonder dat jou dokter dit aangedui het, kan jou toestand of jou kind se toestand vererger.

4. MOONTLIKE NEWE-EFFEKTE

EPILIZINE kan newe-effekte hê.

Nie alle newe-effekte wat vir EPILIZINE gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of indien julle enige ongunstige effekte ondervind terwyl hierdie medisyne geneem word, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg.

Sê onmiddellik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal indien jy enige van die volgende ernstige newe-effekte opmerk:

- allergiese reaksies, wat gewrigspyn, veluitslae en koors (sistemiese lupus eritematose) veroorsaak
- ’n allergie-uitgelokte swelling met pynlike, jeukerige bulte (angio-edeem); meestal rondom die oë, lippe, tong en keel, met asemhalings- en slukprobleme, en soms die hande en voete
- sindroom met medisyne-uitslag, koors, vergroting van die limfknope en moontlike belemmering van ander organe (DRESS-sindroom)

- herhaalde braking, buitensporige moegheid, buikpyn, lomerigheid, swakheid, verlies aan aptyt, erge pyn in die boonste deel van die buik, naarheid, geelsug (vergeling van die vel en die wit van die oë), swelling van die bene, verergering van jou epilepsie of ’n algemene gevoel van ongesteldheid
- erge afname in witbloedselle of beenmurgversaking, soms deur koors en asemhalingsprobleme of herhalende infeksie aangedui
- bloedstollingsprobleme (bloei vir langer as normaal)
- kneusing of bloeding sonder rede
- EPILIZINE kan ook verminderde plaatjie- of rooibloedseltelling (pansitopenie) veroorsaak
- belemmerde geheue en kognitiewe versteurings (veranderings in gemoedstoestand, vergeetagtigheid, gebrek aan konsentrasie)
- verlies aan bewussyn (koma)
- onderaktiewe skildklier, wat moegheid of gewigstoename veroorsaak (hipotiroïdisme)
- probleme met asemhaling en pyn as gevolg van inflammasie van die longe (pleurale effusie)
- veranderings in die bewussynsvlak, bisarre gedrag gepaardgaande met/of nie meer gereelde of erger toevalle, verlies aan dryfkrag, veral indien fenobarbitaal (fenobarbitoon) en topiramaat gelyktydig geneem word of as die dosis EPILIZINE skielik verhoog is
- veranderings in die hoeveelheid ammoniak in die bloed. Simptome van hierdie toestand is naarheid en braking, probleme met balans en koördinasie, gevoel van lusteloosheid of verminderde waaksaamheid.
- verwardheid wat moontlik die gevolg is van verlaagde vlakke van natrium in jou bloed
- ekstrapiramidale versteuring (voel bewerig [tremore], slaperig, wankelrige stap of rukkerige spierbewegings)
- blase met vel-loslating (die vel skilfer af)
- vinnige, onbeheersde bewegings van die oë
- spierpyn en spierswakheid (rabdomiolise)
- ’n toename in die aantal en ernstigheidsgraad van konvulsies.

Dit is alles **ernstige newe-effekte**. Jy kan dringend mediese sorg benodig.

Ander newe-effekte is:

Newe-effekte wat dikwels voorkom

- braking, naarheid (voel mislik) of maagpyn, diarree
- duiseligheid
- gehoorprobleme
- hoofpyn
- haarverlies; wanneer dit teruggroei kan dit meer krullerig wees as vantevore
- hare, insluitend die hare op die liggaam en die gesig groei meer as normaalweg by vrouens (polisistiese ovariële sindroom)
- menstruele veranderings (veranderings in ’n vrou se maandstonde)
- gewigstoename (omdat jou aptyt verhoog mag wees)
- afname in karnitienvlakke (gesien met bloed- en spiertoetse)
- aggressie, agitasie, versteurde aandag
- tinteling of gevoelloosheid van die hande of voete
- gingivale (tandvleis) probleme, veral oorgroei
- seer mond, geswelde mond, mondsere en brandgevoel in die mond (stomatitis).

Newe-effekte wat minder dikwels voorkom

- floutes, hallusinasies (sien, voel of hoor dinge wat nie bestaan nie)
- velreaksies soos veluitslae
- aknee, dieper stem
- veranderings in haarkleur, nael- en naelbedversteurings
- swelling van die voete en bene (edeem)
- nierprobleme, bednatmaak of groter behoefte om te urineer
- urineer baie en voel dors (Fanconi se sindroom)

- abnormale gedrag, rusteloosheid/hiperaktiwiteit en leerversteuring
- belemmerde vrugbaarheid
- afname in liggaamstemperatuur
- beenversteurings, insluitend osteopenie en osteoporose (verdunning van die been) en frakture, is gerapporteer. Bespreek dit met jou dokter of apteker indien jy op langtermyn anti-epileptiese medikasie is, ’n geskiedenis van osteoporose het, of steroïede neem
- dubbelvisie.

Frekwensie onbekend:

- Pelger-Huet-anomalie (’n aangebore bloedtoestand, waar die kerne van die witbloedselle ’n ongewone vorm en struktuur het), wat jou dokter met behulp van ’n bloedtoets sal bepaal.

Kinders:

Die veiligheidsprofiel van EPILIZINE by kinders is vergelykbaar met dié by volwassenes, maar sommige ongunstige reaksies is erger en word meer dikwels by kinders waargeneem. Daar is in besonder ’n risiko van erge lewerskade by babas en jong kinders, veral jonger as 3 jaar oud. Jong kinders het in besonder ’n risiko vir pankreatitis. Hierdie risiko’s verlaag met toenemende ouderdom (sien Waarskuwings en voorsorgmaatreëls). Psigiatriese versteurings soos aggressie, agitasie, aandagsteuring, abnormale gedrag, psigomotoriese hiperaktiwiteit en leerversteuring word hoofsaaklik by kinders waargeneem.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter, apteker of ander gesondheidsorgverskaffer daaroor in.

Rapportering van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan newe-effekte direk by Sanofi se Eenheid vir Farmakowaaksaamheid rapporteer deur ’n e-pos na za.drugsafety@sanofi.com te stuur of 011 256 3700 te skakel.

Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety-toepassing (Medsafety X SAHPRA) en eRapportering-platform (who-umc.org) wat op SAHPRA se webwerf beskikbaar is.

Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van EPILIZINE te verskaf.

5. HOE OM EPILIZINE TE BERG

BERG ALLE MEDISYNES BUITE BEREIK VAN KINDERS.

Bêre EPILIZINE CR in die oorspronklike verpakking by of onder 25 °C.

Beskerm teen lig en vog.

EPILIZINE CR kan bederf indien dit nie korrek bewaar word nie. Dit is baie belangrik om die tablette in die beskermende foelie te hou tot net voordat jy dit neem.

Moenie EPILIZINE CR ná die vervaldatum wat op die verpakking aangedui word, neem of gebruik nie.

Neem alle ongebruikte medisyne of medisyne wat verval het, terug na jou apteker vir veilige wegdoening.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) wegdoen nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat EPILIZINE CR bevat

Die aktiewe bestanddeel is natriumvalproaat.

Die ander bestanddele is:

Etielsellulose, gehidreerde silika, hipromellose en pers deklagie bevattende: hipromellose, titaandioksied, makrogol 400, indigokarmyn-aluminiumlak FD&C Blue No. 2, eritrosien BS aluminiumlak, swart ysteroksied.

Hoe EPILIZINE CR lyk en inhoud van die verpakkings

EPILIZINE CR 200: ongemerkte, langwerpige, pers, filmbedekte tablette, nominale grootte 13,25 x 6,75 mm.

EPILIZINE CR 300: ongemerkte, langwerpige, pers, filmbedekte tablette, nominale grootte 15 x 7,5 mm.

EPILIZINE CR 500: ongemerkte, langwerpige, pers, filmbedekte tablette, nominale grootte 17,25 x 9,75 mm

EPILIZINE CR 200, EPILIZINE CR 300 en EPILIZINE CR 500 tablette word in silwer aluminiumfoelie-stulpstroke, met ’n inligtingsblad, in bedrukte kartonne met 56 of 100 tablette verpak.

Houer van Registrasiesertifikaat

sanofi-aventis south africa (edms.) bpk.

Hertford Office Park, Gebou I, 5de Vloer

Bekkerweg 90, Vorna Vallei

Midrand 2196

Suid-Afrika

Tel: 011 256 3700

Hierdie inligtingsblad is laas hersien

02 April 2025

Registrasienommers

EPILIZINE CR 200: A39/2.5/0038

EPILIZINE CR 300: A39/2.5/0039

EPILIZINE CR 500: A39/2.5/0040

Registrasiedatum

04 Desember 2009.